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I Abstract

The purpose of this project is to develop a system design and fabrication techniques for multiple-channel, physiologically implantable, telemetering systems. The design is to be flexible, allowing several channels of information to be handled simultaneously, and to be able to telemeter a wide range of physiological signals. This report covers the period of March 1967 to September 1967.

The single-channel FM/FM strain-gage system implanted in a dog during the period covered by the previous Semi-annual Report performed well for a period of four months. The strain-gage pickup apparently had a wire breakage occur about four months after implant. The subcarrier, RF circuitry, and magnetic switch have continued to function since this breakage.

A system having four strain-gage pickups was fabricated using micro-miniature standard components. A receiving and demodulating system was constructed for this transmitter. The individual channels had a noise level under one gram and a full scale of over 300 grams of force applied to the pickups. The noise level was measured at the demodulator output.

This four-channel system was implanted and performed satisfactorily initially. After a period of one week the water-proofing broke down. The transmitter was reclaimed and repaired. It will be implanted again with better water-proofing and a new battery pack.

Hybrid integrated circuits have been designed and fabricated for a four-channel strain-gage system. These are at present being tested in a breadboard unit and are functioning well with the addition of a few external components. A few differences have arisen between the discreet component

system and the integrated circuit version. These will lead to modifications of some of the integrated circuits' design. With the addition of a few standard components, the present integrated circuits will be packaged for a four-channel strain-gage unit.

Circuitry has been breadboarded and incorporated into the integrated circuit test unit which will allow EKG signals to be handled. The breadboard has 8 information channels plus sync and AGC channels. The receiving and demodulating system is being expanded to handle this 8-channel system. As soon as the EKG preamps are proven they will be fabricated in integrated circuit form.

II Background

The requirements that the system design must satisfy are:

1. Suitable for implanting in small monkey or a dog.

2. Simultaneously telemeter several physiological signals.

3. Transmit to a receiver not more than 20 feet away.

4. Flexible - expandable to include different numbers of channels as necessary.

These requirements set up guide lines for the circuitry as:

1. Simple, non-critical, reliable.

2. Miniature construction of circuitry must be possible.

3. Minimum power drain by circuits.

4. Circuitry must accept inputs from:

    a. resistive bridges (thermistors, strain-gages, etc.)

    b. electrical signals (EKG, EMG, EEG)

    c. other transducers.

With these requirements in mind, the following procedural outline has been followed:

1. Basic system design worked out.

2. Prototype system built and tested.

3. Preliminary implant to evaluate some circuitry.

4. 4-Channel strain-gage unit built and implanted using micro-miniature standard components.

5. Fabrication equipment purchased and put into operation for integrated circuit fabrication.

6. Hybrid integrated circuits designed and built.

7. Testing and evaluation of transmitter using hybrid integrated circuits.

8. Implant of transmitter using hybrid integrated circuits and some microminiature standard components as necessary.

9. Modification of integrated circuits' designs as necessary.

10. Breadboard and test unit with 8 channels, including 6 strain-gage channels and two electrical-signal channels.

11. Fabrication of integrated circuits for 8-channel unit.

12. Develop receiving and demodulation system in parallel with the above work.

During the period of this report, a four-channel transmitter for strain-gage pickups was fabricated. The circuitry was reduced to hybrid integrated circuit form and the hybrid integrated circuits built for a four-channel strain-gage system. The receiving and demodulating system was constructed and tested for these transmitters. The standard component version was implanted and worked for a period of a week until the waterproofing broke down. It was recovered and repaired and will be reimplanted.

III Results of Single - Channel Transmitter Implant

A single-channel strain-gage transmitter was implanted in a dog. This test was made to evaluate the RF link, the magnetic switch, mercury battery pack, and packaging and waterproofing methods. The system was an FM/FM type with a subcarrier whose frequency was controlled by the strain-gage. The output of the subcarrier modulated the RF carrier frequency.

This system worked well for a period of four months. At the end of this period a wire lead to the strain-gage apparently broke. This caused the subcarrier frequency to go to its lower limit. The subcarrier still oscillated and the RF unit still broadcasted when turned on by the magnetic switch. The unit was functioning this way about two months after the wire breakage. The transmitter will be checked periodically to study the life time of the remaining circuit functions.

IV Review of System Features and Operation

The transmitting and receiving systems were discussed in the previous report. The transmitter circuitry is made up of the following sections:

1. Self-starting ring oscillator.
2. Signal conditioning amplifiers.
3. Multiplexing gates.
4. RF unit.
5. Power pack with magnetic switch.

The ring oscillator controls the multiplexing gates and also switches the power to each signal conditioner as it is being used. The RF unit transmits the sampled signals to the external receiver. The magnetic switch allows the transmitter to be turned on and off when desired from the outside of the animal having implant.

The receiving circuitry is made up of the following sections;

1. Ring oscillator
2. Sync pickoff
3. Automatic gain control
4. D C restorer or clamping circuit
5. Sample and hold demultiplexing gates
6. Automatic lock-in for sync and AGC.

The demultiplexing gates are controlled by the ring oscillator. The ring oscillator is synchronized with the transmitted signal. The DC restorer reinserts the DC level to the signal and the AGC circuit insures correct amplitude. The automatic lock-in circuits insure that sync and AGC lock will occur at initial turn-on and also in the case that lock is lost during operation.

V Four-Channel, Micro-Mineature, Standard-Component Unit

This unit was built up on a printed circuit board. The components used were:

1. NPN transistors -- GE Microtab
2. PNP transistors -- Amperex LID's
3. Resistors -- 30 mw units from British Radio Electronics, Inc.
4. Capacitors -- Chip capacitors from Westcap
5. Integrated Circuits -- Fairchild μA 702's in flatpacks

The dimensions of the electronic circuitry, less RF unit, battery pack and magnetic switch were 1 1/8" x 2 1/4" x 1/4" including epoxy potting material. Figure 1 shows the component side of this circuit board. Figure 2 shows the underneath side of the board and Figure 3 gives a picture of the size of the unit with four strain-gages attached.

This transmitter, complete with RF unit, consumes about 30 milliwatts of power. This will give between 100 and 125 hours useful operation with the battery pack to be used when the system is implanted. Although the signal conditioners would draw about 15 milliwatts of power each if run continuously, gating their power supplies allows all of them to operate on about 10 milliwatts. This occurs since each is on for 1/6 of the time, and four circuits operated in this manner consume 2/3 of the power each alone would draw if operated continuously. The RF unit draws about 10 milliwatts and the ring counter, sync, and AGC circuitry consume another 10 milliwatts.

The moisture-proofing method used on the first implant (the FM/FM, single-channel system) and on the repaired 4-channel unit is to pot the electronics in epoxy and bring only bare, degreased, solid wires through the epoxy.

The epoxy bonds well to the wires and doesn't allow any moisture to enter. The reason the first implant of the 4-channel unit failed was that a silastic tube containing wires to the outside didn't have a complete epoxy seal between it and the circuit board. This allowed moisture (body fluids and/or sterilizing fluids to penetrate and short out part of the electronics.

The epoxy package is then wrapped in nylon mesh and silk sutures used to tie the mesh in place. Pairs of ends of these sutures, about 10 inches in length, are brought out through the medical grade silastic outer covering which is applied over the mesh and sutures. A type A adhesive covering is applied to the epoxy package before this outer covering so that the silastic will bond to the epoxy.

The unit is then sterilized for 48 hours in Zephiran Chloride and soaked in sterile distilled water for another 48 hours to get rid of the Zephiran Chloride. The unit is then stored in sterile distilled water until being implanted.

The above packaging and sterilization have not given any evidence of infection or reaction in the two implants to date.

The input transducers were 1000 ohm silicon strain gages. These were packaged by the Parke-Davis Research Center in Ann Arbor, Michigan, for suturing on to the stomach and other portions of the gastro-intestinal tract. The system was calibrated by applying known weights to the pickups. A weight was applied to each gage and the demultiplexed output measured. System sensitivities and noise levels were thus determined. Full scale for the channels was about 300 grams with a noise level of 1 gram or less for each channel. The frequency response of these channels for these tests was about DC to 100 H_z determined by the pen recorder on the outputs. There was no measurable crosstalk between the channels.

There was no noticeable performance change for the system from bench tests to implanted location. The transmitter was monitored during surgery and immediately following. The activity patterns obtained were similar to those obtained by wired systems for the same pickup locations. Typical post-operative activity patterns are given in Fig. 4.

The construction method outlined aboved is very tedious to perform. The printed circuit board has line widths of a few thousandths of an inch and similar spacing between conductors. The board required is also double-sided requiring a high degree of accuracy in its construction. The holes drilled in the board are 0.007 inches and 0.010 inches. These must be carefully drilled under a microscope with the aid of a precision miniature drilling machine.

The components must be handled, inserted, and soldered into place under a microscope. The components have dimensions ranging from 0.030 inches to 0.100 inches with lead diameters of 0.005 inches and .007 inches.

This method of packaging allows tailoring of individual component values and a finished package size about equal to that of an integrated circuit unit. The disadvantages are the tedium and difficulty of fabrication and trouble-shooting. For a system containing a total of 10 to 20 components, this is not too bad a job but for one containing over 150 in a 2 square inch area it is poor.

Integrated circuits are very applicable to this type of system. Individual functional blocks can be fabricated and tested. The faulty units are rejected at this stage. A small number of these blocks are then packaged together with 60% to 80% of the interconnections already made within the flatpacks. The fewer number of connections to be made the better the reliability of the finished product and the flatpacks with faulty internal connections are discarded or repaired as a unit.

Another feature is that the flatpacks can be mass-produced with the aid of mechnical equipment. Then they will be interconnected manually on the printed circuit board. For the standard-component method, all interconnections are manual and more subject to failure.

The circuitry of the 4-channel strain-gage transmitter was divided into functional blocks. In the system design some of these blocks repeat so that quantities of some of the blocks are used. These functional blocks were laid out and fabricated in $\frac{1}{4}$ " by $\frac{3}{8}$ ", 14-lead flatpacks using transistor, resistor, and capacitor chips. Figure 5 shows an open flatpack containing one stage of the ring oscillator one sealed flatpack containing the same circuit.

The component chips are mounted by eutectic bonding on a gold pattern which is fired into a ceramic substrate. The substrate with the mounted chips is put into a flatpack and then 1 mil gold wires are used to interconnect the circuit components and to make connection to the leads of the flatpack. Then the circuit is tested. If the circuit works properly, a bid is sealed on to the flatpack. The circuit is again tested. If it is still good it is color-coded to identify it.

Integrated circuits have been fabricated to build a 4-channel strain-gage transmitter. They are currently being tested in a breadboard unit. In the tests, it was necessary to add a few components external to the flatpacks. This is necessary since the flatpacks circuits have slightly different characteristics from the standard component versions. Subsequent integrated circuits will be modified by the results of these tests. The first version of the integrated circuits will be used along with the necessary additional components to package a 4-channel unit for 5000 ohm strain gages.

The following is a list of integrated circuit designs as they are developed at the present writing. These circuits have been fabricated and are in operation:

No. 201	Ring oscillator stage, reset to off, Figure 6.
No. 202	Ring oscillator stage, reset to on, Figure 7.
No. 204	"And" circuit for ring oscillator, Figure 8.
No. 205	Ring oscillator driver, Figure 9.
No. 206	RF stage, Figure 10.
No. 207	Strain-gage signal conditioner, Figure 11.
No. 208	Frame sync generator, Figure 12.
No. 209	Automatic reset generator, Figure 13.
No. 210	Electronic-latching, magnetic-switch-controlled power switch Figure 14.

Some modifications of the above circuits are being fabricated and tested at present. These tests are made in the operating broadboard of integrated circuit units.

VII 4-Channel Integrated Circuit Transmitter.

A transmitter to handle four 5000 ohm strain-gage pickups will be fabricated using the present line of integrated circuits and a few micro-mineature standard components where necessary. This unit will use a printed circuit board to interconnect the flatpacks. The flatpacks will be mounted vertically on edge in the printed circuit board. The package size for everything except the battery pack will be approximately 1/2 inch by 1 inch by 2 inches or smaller. Further flatpack development will reduce a 4-channel unit like this one to 1/2 inch by 1 inch by 1 inch. These dimensions include epoxy potting for water-proofing.

This system will operate with a power supply drain of about 25 milliwatts according to tests of the integrated circuit breadboard unit. Further integrated circuit refinement will quite possibly lower this.

VIII 8-Channel System Tests

The basic transmitter system is expandable by merely inserting extra stages into the ring oscillator and driving additional signal conditioners with the additional stages. The breadboard unit for testing the flatpacks will accept up to 10 ring oscillator stages, driving 8 signal channels, plus sync and AGC. For a 4-channel system the ring oscillator is closed with six stages.

This breadboard unit is being used to test out preamp circuits for EKG pickup. Breadboard preamps are inserted into the signal conditioner slots and this allows the direct electrical signals to be transmitted through the systems. The receiving and demodulating system is being expanded to handle these additional channels.

Preamps are under study which have a bandwidth of 1 H_z to 200 H_z and a tangential noise level for the whole systems, referred back to the input of approximately 3 microvolts. The input impedance of the circuit presently under study is approximately 250 kΩ. This noise level is based on the present state of the demodulator circuitry with the input of the transmitter channel driven by a signal generator.

A novel technique developed in the work on these preamps is a method to multiply the input impedance of a differential amplifier by the reciprocal of the duty cycle of the amplifier's power supply gating.

Figure 15 gives a sketch of this circuitry. The input resistors, R_1 and R_2, along with the capacitors, C_1 and C_2, form a low pass filter. The differential amplifier is gated so that no input current flows when the amplifier's channel is not being used. The capacitors only see the amplifier's input impedance during the period that the amplifier is being used. The capacitor charges for 100% of the time and discharges into the differential amplifier's input a fraction of the time, equal to the duty cycle. Since the capacitor is a storage element, it integrate out the effect of the amplifier's loading, giving an equivalent load (full-time) equal to its input impedance divided by the duty cycle. This effect has been verified in operation.

Preamps are being studied which use a low-power, 100% duty cycle, amplifier capacitor - coupled to one with a gated power supply. This is necessary to get the required gain for EEG gain and EMG signals. The capacitor coupling is necessary to block DC unbalances in the first stage from saturating the second stage. An RC low-pass filter between the stages aids in keeping the high-gain overall amplifier stable at high frequencies. It should be possible to capacitor-couple two cascaded amplifier stages and gate both stages' power supplies. This is subject to further development and will aid in minimizing power drain.

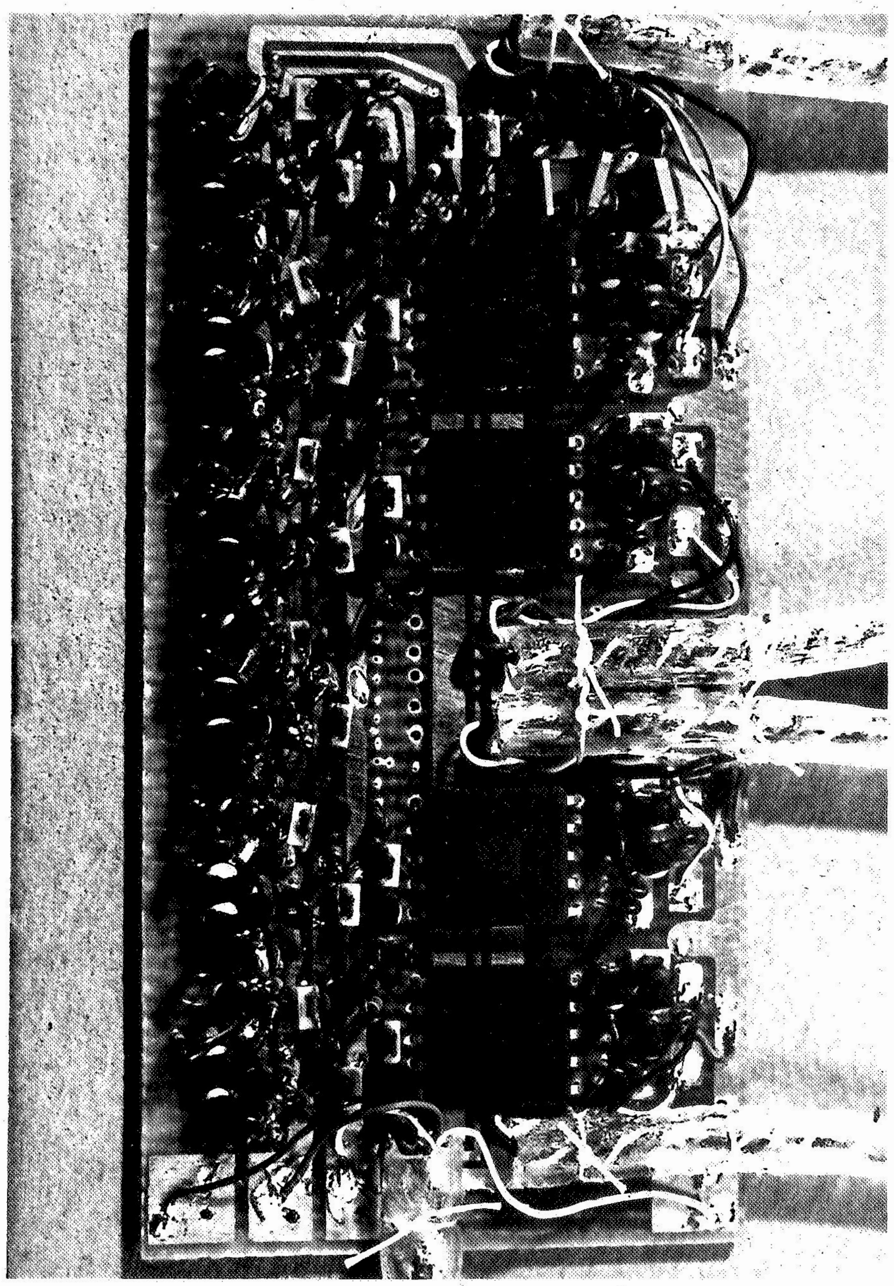

Figure 1. Component side of printed circuit board for 4-channel microminiature standard component transmitter.

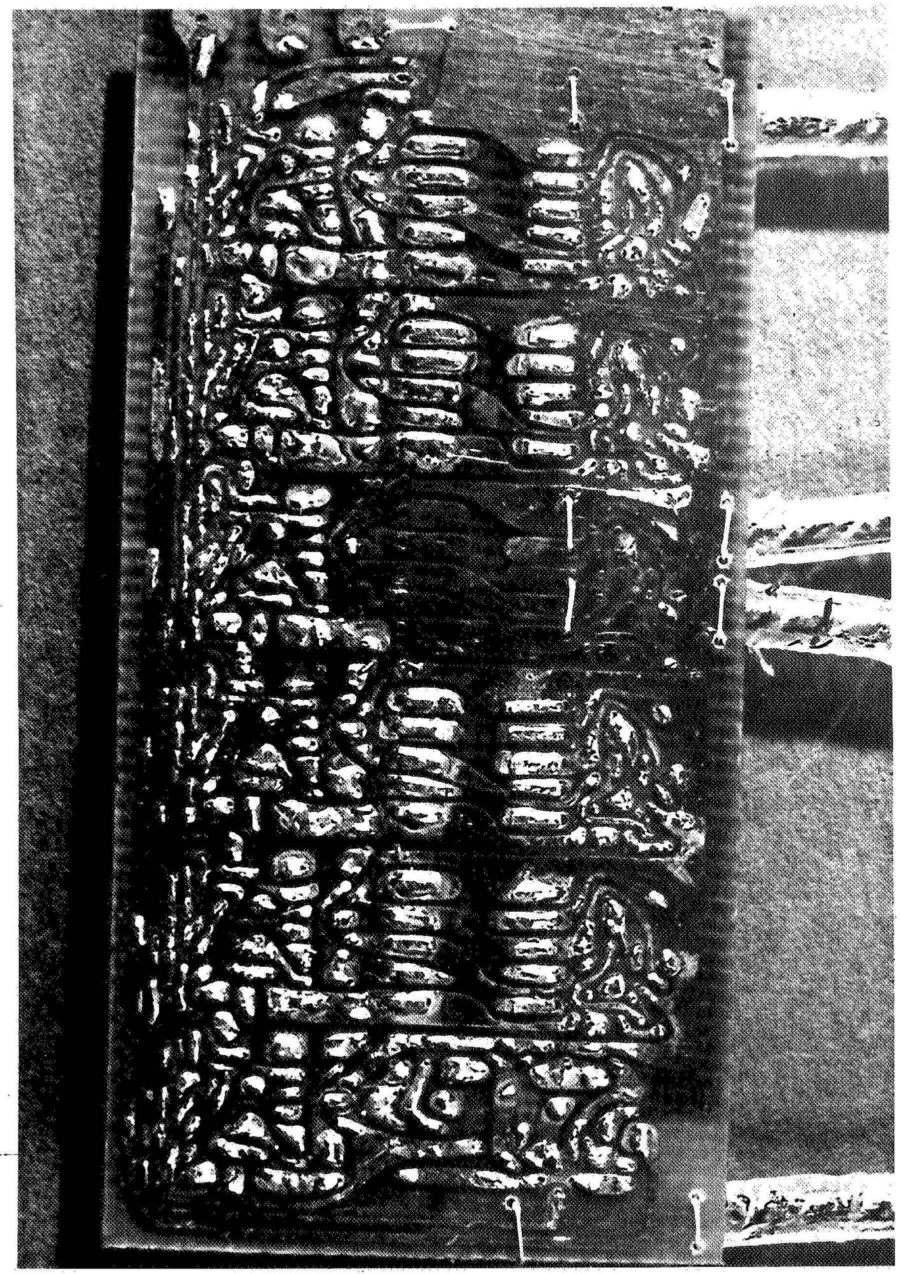

Figure 2. 4-Channel transmitter unit showing side of circuit board opposite components.

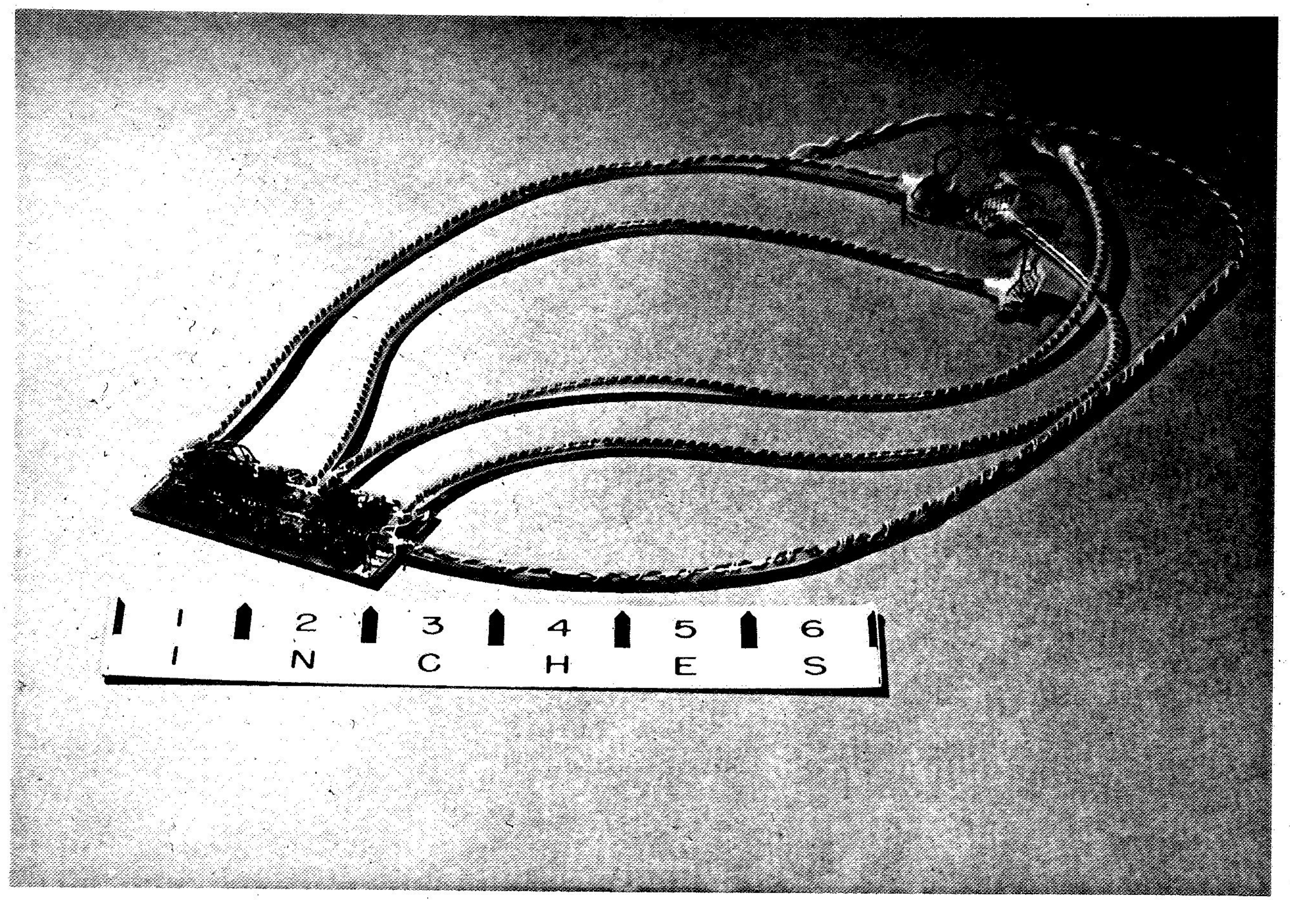

Figure 3. 4-Channel transmitter unit with strain-gage pickups.

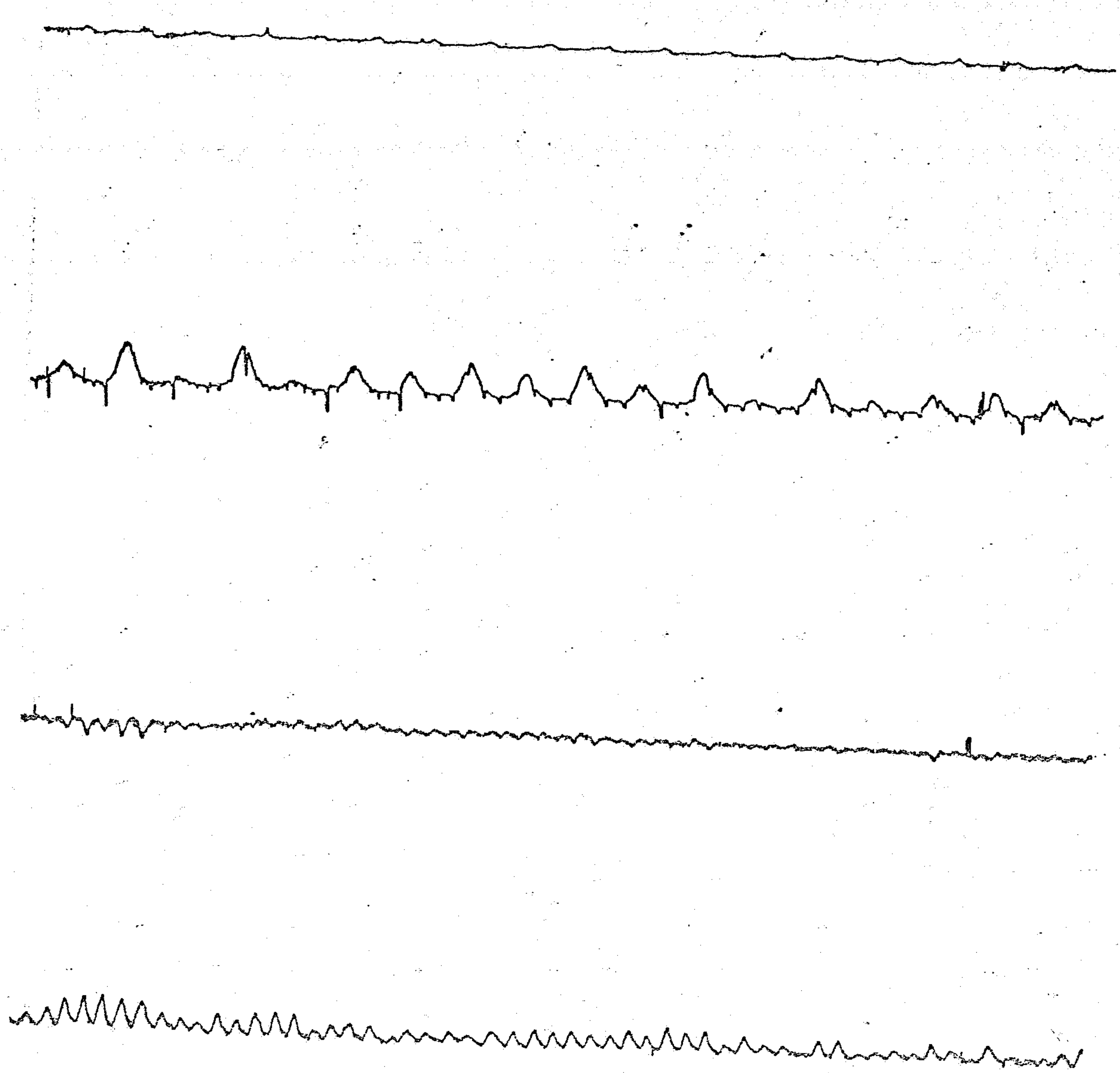

Figure 4. Section of the post-operative recording from 4-channel strain-gage system. The pickups were attached as follows:

1. Stomach antrum, circular
2. Stomach antrum, longitudinal
3. Duodenum, circular
4. Duodenum, longitudinal

This record was made 15 August, 1967 at the Pharmacology Department, University of Michigan.

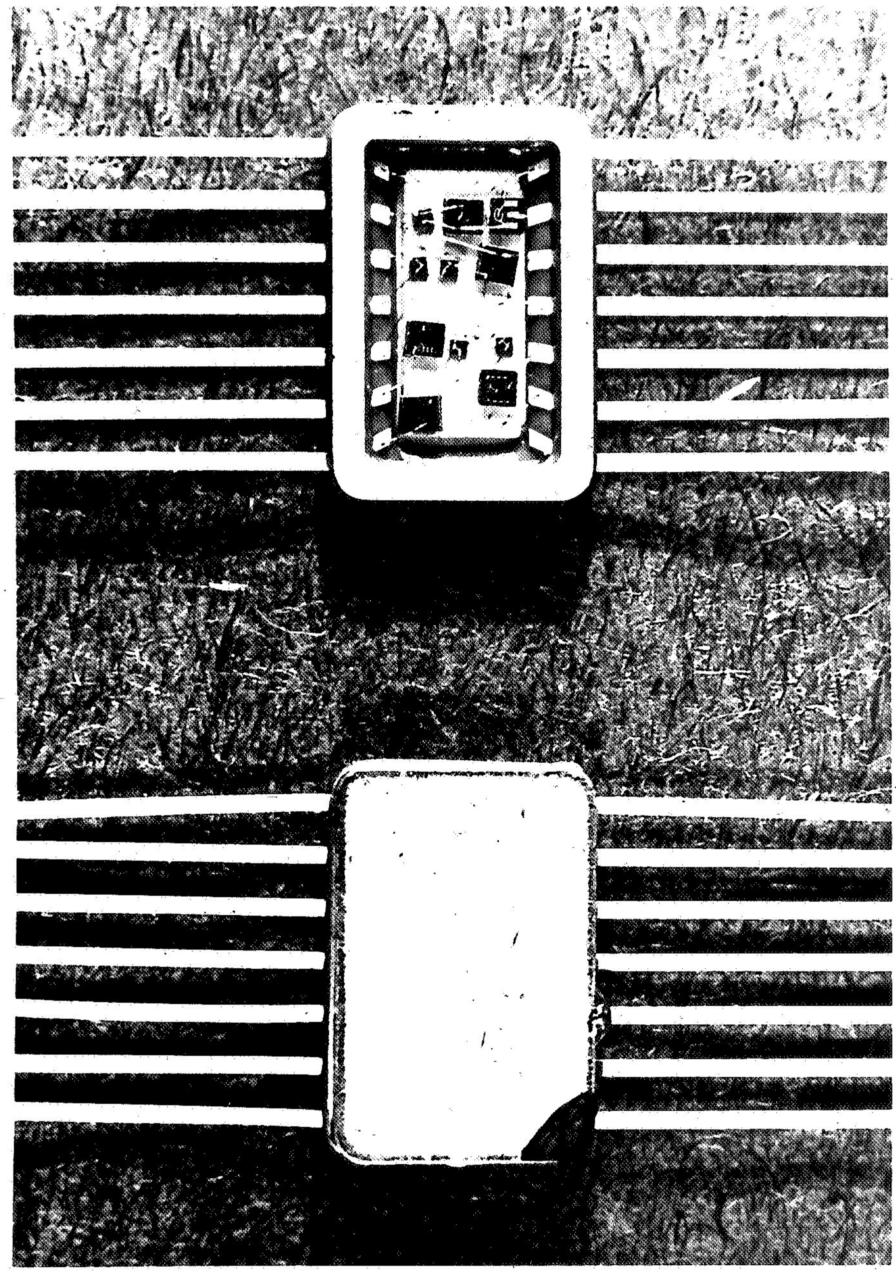

Figure 5. Hybrid integrated circuits mounted in flatpacks. The open flatpack shows resistor and transistor chips mounted on a ceramic substrate and interconnected with .001" gold wires.

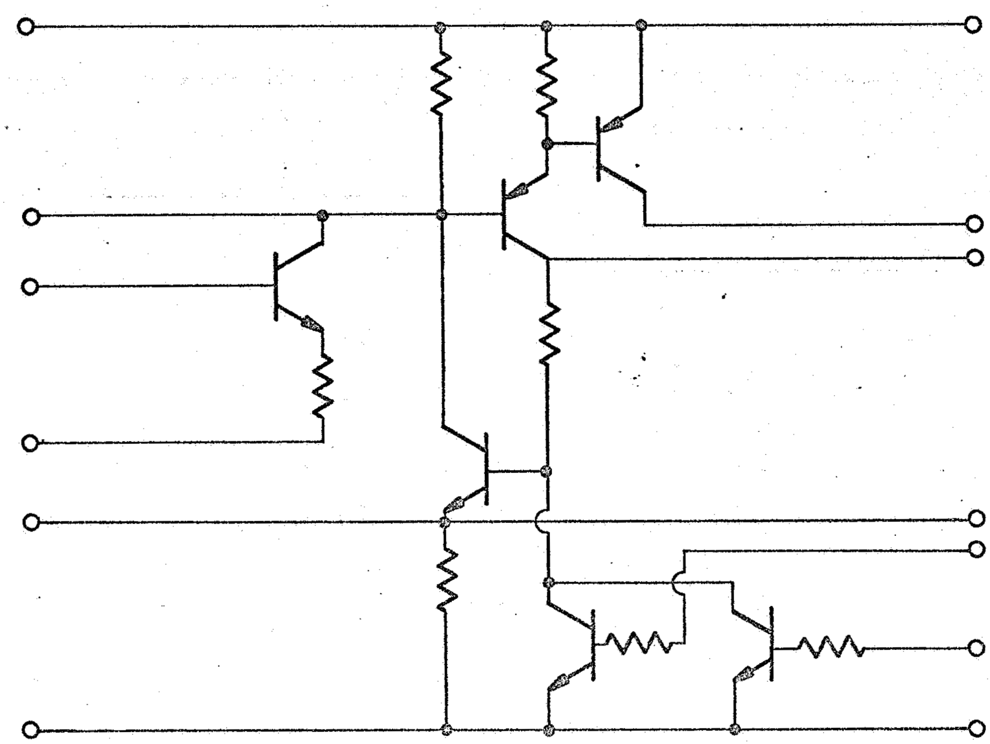

Figure 6. Ring oscillator stage with reset-to-off input. Flatpack circuit No. 201.

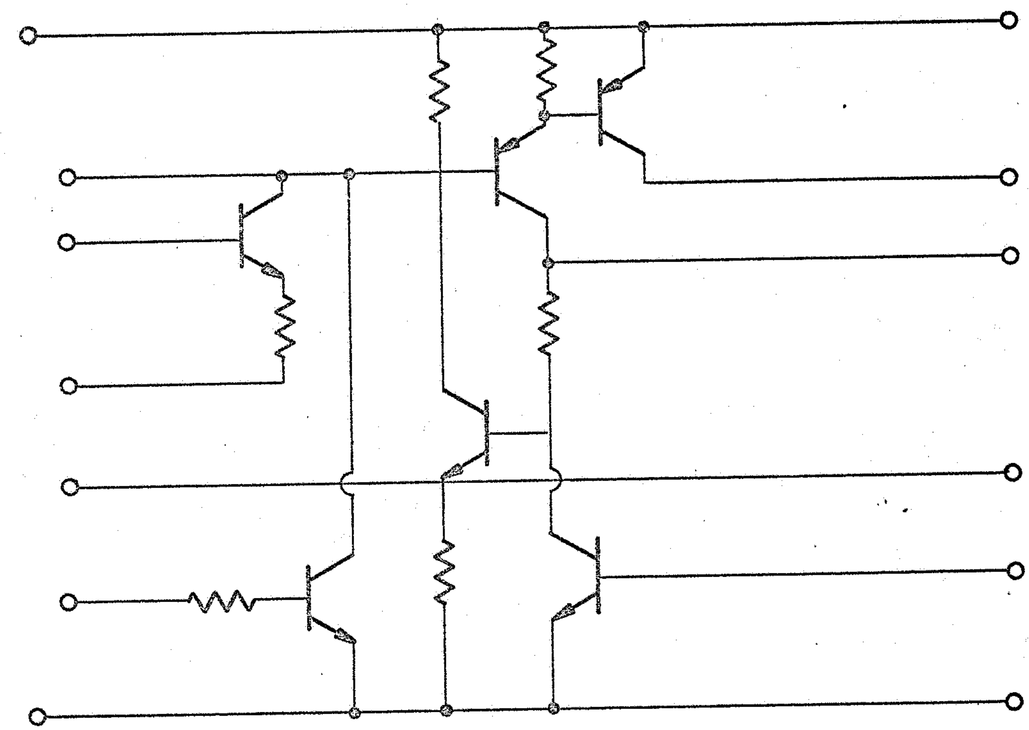

Figure 7. Ring oscillator stage with reset-to-on input. Flatpack circuit No. 202.

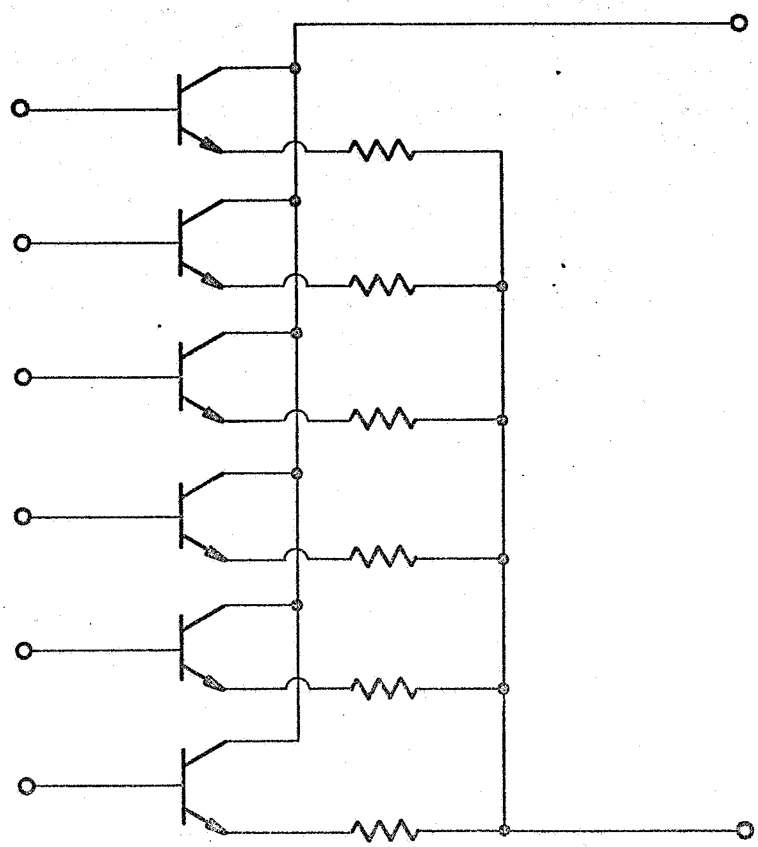

Figure 8. "And" circuit for ring oscillator. Flatpack circuit No. 204.

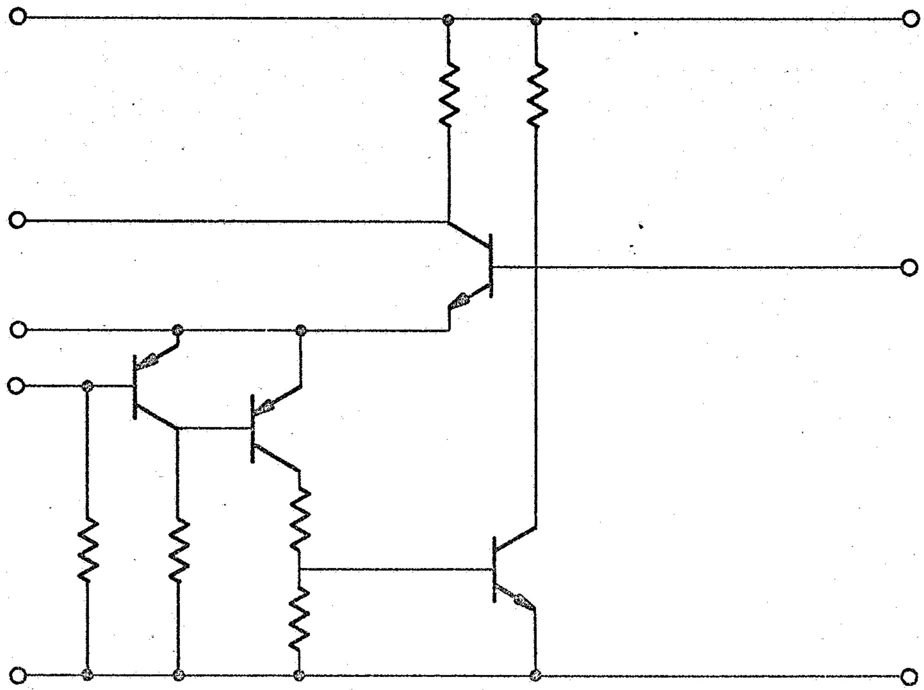

Figure 9. Ring oscillator driver stage. Flatpack circuit No. 205.

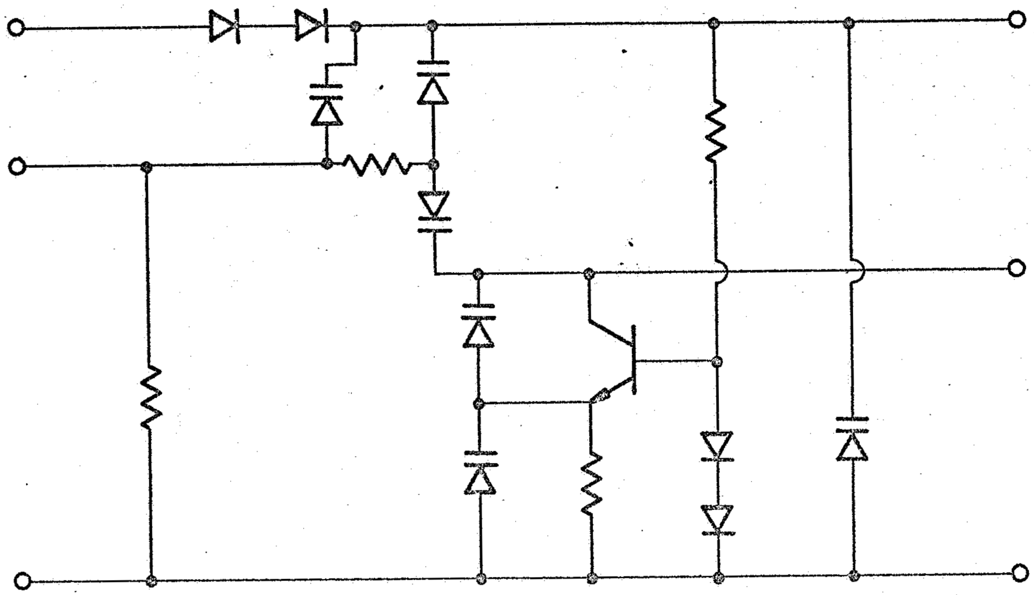

Figure 10, RF unit. Flatpack circuit No. 206.

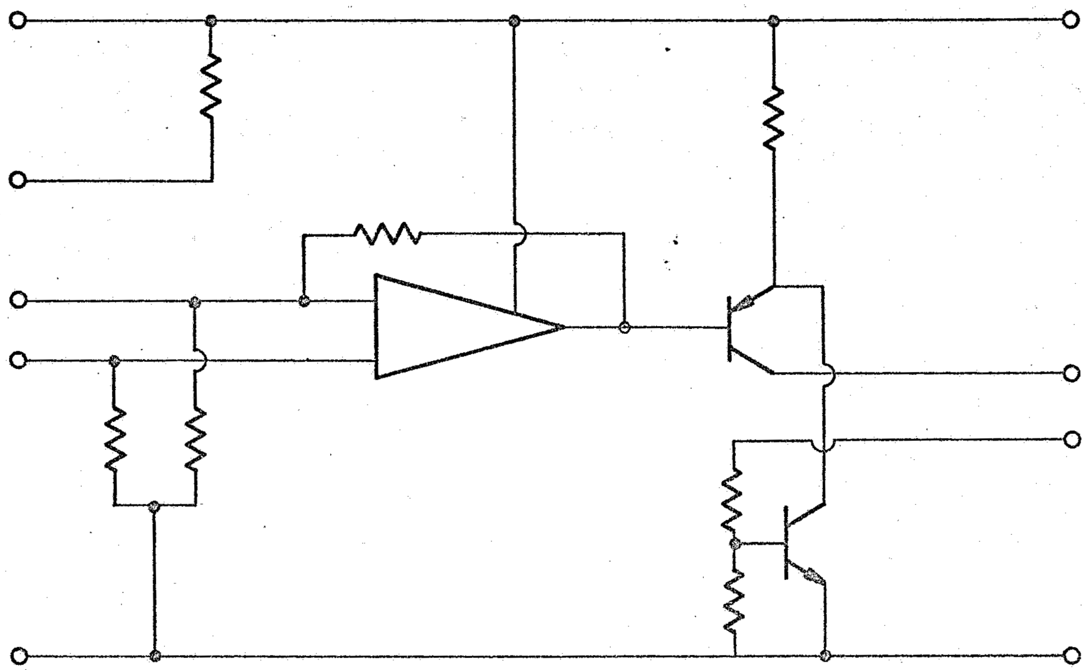

Figure 11. Strain gage amplifier and multiplexing gate. Flatpack circuit No. 207.

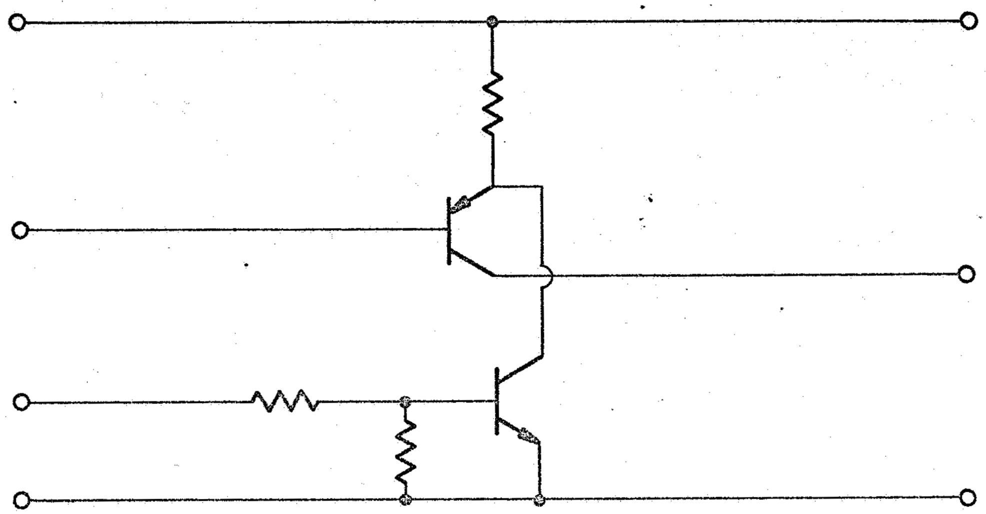

Figure 12. Frame sync signal generator. Flatpack circuit No. 208.

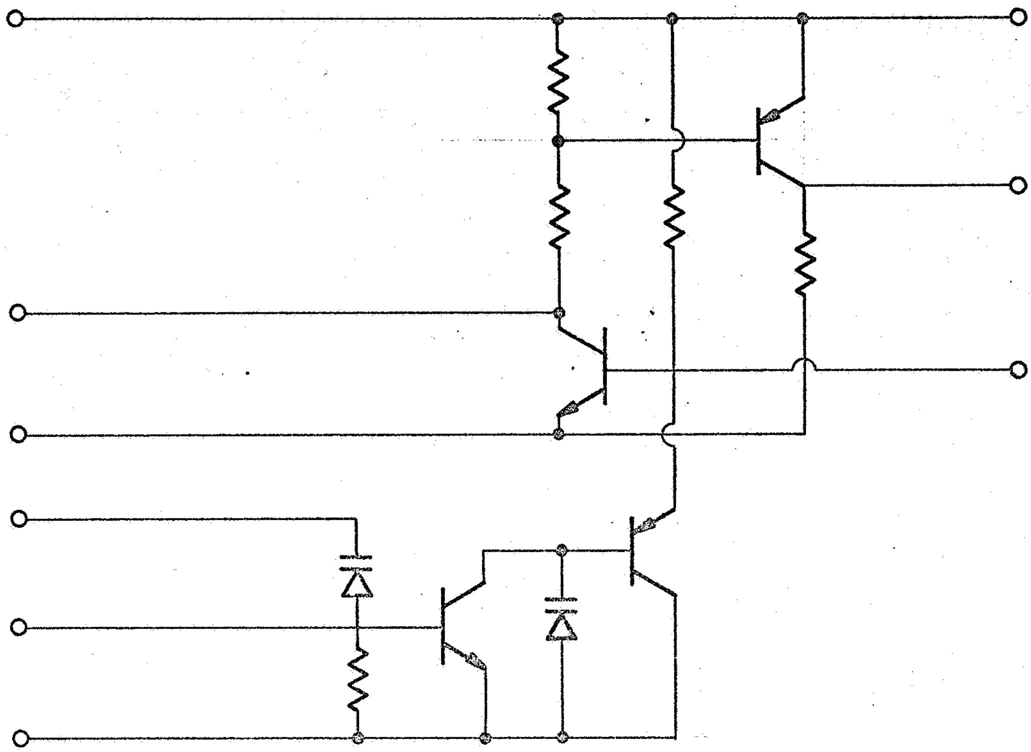

Figure 13. Automatic reset stage for ring oscillator. Flatpack circuit No. 209.

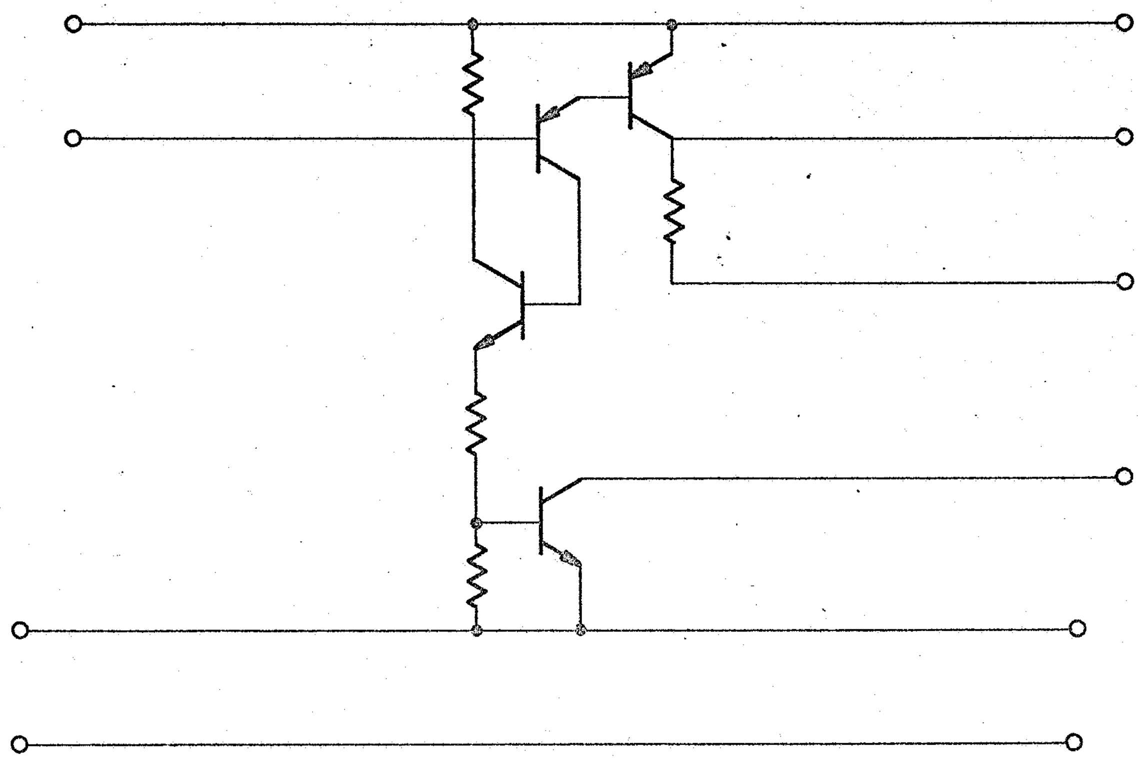

Figure 14. Electronic latching, magnetico-switch-controlled power switch. Flatpack No. 210.